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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/750,079
Filing Date: December 31, 2003
Appellant(s): FARIABI, SEPEHR

Gunther O. Hanke
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed May 22, 2009, being treated as a supplement to the appeal brief filed March 30, 2009, appealing from the Office action mailed October 31, 2008.

The appeal briefs do not have separate sections/pages for the Evidence Appendix and the Related Appeals Appendix, but pages 17 of the briefs do state "none" for their contents. These deficiencies are considered minor because pages 17 of the briefs clearly indicate that the sections were to have no substantive content; see MPEP 1205.03.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct. A copy of the appeal claims can be found in the claims appendix of the March 30, 2009 appeal brief.

(8) Evidence Relied Upon

5,891,193	ROBINSON et al	4-1999
5,824,077	MAYER	10-1998
4,856,516	HILLSTEAD	9-1989
5,217,483	TOWER	6-1993
4,300,244	BOKROS	11-1981

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 37-50, 53, 54, 56-76, and 82-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al (US 5,891,193) in view of Mayer (US 5,824,077). Robinson meets the claim language where the stent of Robinson has a

relaxed state such that it will not self expand, but the stent material is clearly capable of being bent (permanently deformed) to form the stent; see column 5, lines 31-51. Therefore, the stent is plastically deformable and could be expanded to a state where there would be no bends (37) in the wires (see Figure 4); this unbent expanded diameter reads on the "diameter suitable to hold open the coronary artery" as claimed. Particularly, the size of a coronary vessel varies depending upon the particular patient being treated, and thus, the size of the device as claimed is met by Robinson's device which is also balloon expandable to an unbent form of the segments (33) of Figure 4. The unbent form and the other forms thereof are the size of some individuals. Additionally, self-expansion depends upon how the device is used and how it is biased. For this reason, the Examiner maintains that the claim language pertaining to deformation characteristics is read on by Robinson's device as it is disclosed.

The claimed alloy of the claimed stent is extremely similar to the material (MP35N from Carpenter Technology) of Robinson's device; see Robinson on column 5, lines 34-38 and see the present specification on page 13. However, Robinson fails to disclose an alloy containing iron, tungsten, or manganese as claimed.

Mayer teaches that MP35N was known to be closely related and interchangeable with ELGILOY that does contain iron; see column 3, line 60 to column 4, line 3. Therefore, it is the Examiner's position that it would have been clearly obvious to an ordinary artisan to utilize ELGILOY as the alloy of Robinson for the reason it was chosen over MP35N by Mayer. Alternatively, it would have been obvious to encase the MP35N stent of Robinson with ELGILOY in order to improve the mechanical properties

or for the same reasons that Mayer chose ELGILOY over MP35N as the casing material; see the abstract of Mayer.

With regard to the limitations of claim 37, due to the fact that permanent bends can be put in the wires of Robinson, the Examiner asserts that there is inherently a state of compression that would plastically deform the stent of Robinson since the low profile configuration has no limit and includes placing a plastically deforming amount of pressure on the stent to compress it.

With regard to claim 50, Robinson fails to disclose the percentage of nickel claimed. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to utilize a 2% nickel alloy because Appellant has not disclosed that doing so provides some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Appellant's invention to perform equally well as a stent. Therefore, it would have been an obvious matter of design choice to modify Robinson to obtain the invention as specified in the claims.

With regard to claim 59, Appellant and the Board are directed to Figure 2 of Robinson.

With regard to claims 60 and 61, the aspect ratio claimed is considered be to be broad because it is associated with the modifier "about." For this reason and upon inspection of Robinson's figures, the Examiner determined that the claimed aspect ratios claimed are met by Robinson; see Figure 2 and see Figure 4 for the ratio of two to one.

With regard to claims 54, 62-71, and 75, the electrochemical polishing step is considered to be a product-by-process limitation. Since the degree that this step is performed is not specified, the Examiner posits that it would not result in a product that is different that that disclosed by Robinson; see MPEP 2113, which is incorporated herein by reference. Alternatively, the Examiner asserts that the claimed invention, if made different by this process step, is only made slightly different from a device made without electrochemical polishing. For this reason, the claim language is considered to be at least clearly obvious in view of Robinson alone.

With regard to claims 70 and 71, the aspect ratio claimed is considered be to be broad because it is associated with the modifier "about." For this reason and upon inspection of Robinson's figures, the Examiner determined that the aspect ratios claimed are met by Robinson.

With regard to claims 68, 69, and 76, the cold working or age hardening step is considered to be a product-by-process limitation. Since the degree that this step is performed is not specified, the Examiner posits that it would not result in a product that is different that that disclosed by Robinson; see MPEP 2113, which is incorporated herein by reference. Alternatively, the Examiner asserts that the claimed invention, if made different by this process step, is only slightly different from a device which was not cold worked or age hardened. For this reason, the claim language is considered to be at least clearly obvious in view of Robinson alone.

With regard to claims 84 and 85, the step of cutting voids from a member is considered to be a product-by-process limitation. Since Robinson also discloses a stent

with voids therein, the Examiner posits that process of cutting would not result in a product that is different that that disclosed by Robinson; see MPEP 2113, which is incorporated herein by reference. Alternatively, the Examiner asserts that the claimed invention, if made different by this process step, is only slightly different from a device made a different way with wires. For this reason, the claim language is considered to be at least clearly obvious in view of Robinson alone.

Claims 51 and 52 are rejected under 35 U.S.C. 103 as being unpatentable over Robinson et al (US 5,891,193) and Mayer (US 5,824,077) as applied against claim 37 above, and further in view of Hillstead (US 4,856,516) or Tower (US 5,217,483). Robinson et al as modified by Mayer meets the claim language except for the transverse diameter of about 0.003 inches. However, Hillstead (see column 3, lines 43-45) and Tower (see column 2, lines 34-43) both disclose stents constructed of wires having a diameter (which would be the transverse diameter) of about 0.003 inches. Hence, it is the Examiner's position that it would have been obvious to construct the Robinson device with wires of about 0.003 inches for the same reasons that Hillstead and Tower do the same and in order have a low profile for the stent.

Claims 55 and 77-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson et al (US 5,891,193) and Mayer (US 5,824,077) as applied against claim 37 above, and further in view of Bokros (US 4,300,244). Robinson fails to disclose the use of a biocompatible coating thereon. However, Bokros teaches that it was known to coat similar cardiovascular implants with biocompatible coating in order to render them more biocompatible; see column 2, lines 16-24. Therefore, it is the Examiner's position

that it would have been obvious to coat the Robinson device with a biocompatible coating to make it more biocompatible.

(10) Response to Argument

GROUND I

On page 12 of the brief filed May 22, 2009, the Appellant argues that "each and every claims calls for a balloon-expandable stent to be formed of a certain alloy wherein such alloy requires the stent to undergo plastic deformation in order to attain its expanded state with a coronary artery." However, this characteristic is not positively required for claim 52 that merely requires "an interior chamber **configured to receive** an expandable member for plastically expanding the stent from a first low profile delivery configuration to a second radially expanded configuration." Furthermore, the other **10** independent claims do not require exactly require "the stent **to undergo plastic deformation** in order to attain it expanded state within a coronary artery", but rather, "the stent has a first low profile configuration for delivery and a second radially expanded configuration and **is plastically deformable** from the first low profile delivery configuration to the second radially expanded configuration, the second radially expanded configuration having a diameter suitable to hold open the coronary artery." (see claim 37)

Next, the Appellant argues that there is no suggestion that plastic deformation can occur within a coronary artery; see page 13 of the brief. However, this argument is based upon where the device is intended to be utilized and not on any particular structure. One could reasonably utilize the Robinson device in a coronary artery where

the device is sized to expand as set forth in some of the claims. That is, the stent could be plastically deformable and could be expanded to a state where there would be no bends in the wires; this unbent expanded diameter reads on the "diameter suitable to hold open the coronary artery" as claimed.

The Appellant also argues that the elasticity of Robinson is sufficient to allow its expansion to the expanded configuration. The Appellant seems to have confused what the Examiner considers the expanded configuration. Specifically, the first configuration as claimed is the same as the expanded configuration of Robinson shown in Figure 4. The claimed second radially expanded configuration is not shown in Robinson but would be a configuration of the bends (37) of Figure 4 being completely unbent.

On page 15 of the brief, the Appellant argues that both references are "for use in self-expanding applications due to the material's inherent elasticity." Again, the Appellant relies upon how the device is intended to be utilized rather on the actual structure of the device. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, than it meets the claim.

Next, the Appellant argues that "without the proper treatment of the alloy prior to its use as described in the patent application . . . it simply doesn't have the ductility that is necessary for it to undergo plastic deformation." However, the claims fail to teach the specific ratios of components and particular treatments that result in this alleged property. The Examiner shifted the burden to Appellant to show an unobvious

difference between the claimed invention and the closest prior art (see MPEP 2112 and 2112.01 that are incorporated herein by reference), but the Appellant failed to provide such evidence. In other words, since substantially the same material composition is utilized by Robinson as that claimed, the claimed property of plastic deformation would be inherent thereto. Therefore, the burden of showing that the claimed alloys, within the entire range encompassed by the claims, have plastic deformation properties distinct and unobvious to those of Robinson rests with the Appellant.

Finally, the Appellant argues that expansion well beyond the diameter of an artery would render it unsuitable for its intended use. However, this argument relies on the particular artery that the device is **intended to be utilized**. For example, if a stent designed for a child were used in an adult, it could be expanded to have no bends (37) and would be suitable to hold open the coronary artery of that adult.

GROUND II

The Appellant relies on the arguments presented against the first ground of rejection so these claims should stand or fall therewith.

GROUND III

The Appellant relies on the arguments presented against the first ground of rejection so these claims should stand or fall therewith.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Paul Prebilic/

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